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IN THE SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1996

COMMITTEE OF DENTAL AMALGAM ALLOY MANUFACTURERS AND DISTRIBUTORS AND DENTSPLY INTERNATIONAL, INC., *Petitioners*,

v.

RICHARD A. BECKER, DIRECTOR OF THE OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT, DANIEL E. LUNGREN, ATTORNEY GENERAL OF THE STATE OF CALIFORNIA, AND ENVIRONMENTAL LAW FOUNDATION, *Respondents*.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

RESPONDENTS' BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

On June 26, 1996, this Court decided in *Medtronic* v. *Lohr*, __ U.S. __, 116 S. Ct. 2240 (1996), that the prescription device labeling requirements of the Medical Device Amendments to the Federal Food, Drug and Cosmetics Act, contained in 21 C.F.R. section 801.109, were too general to preempt common law failure to warn claims; and that common law failure to warn claims were not developed "with respect to" medical devices and therefore were not the type of state requirements that Congress and the FDA intended to be preempted by the MDA. The question presented here is:

Whether, in light of this Court's decision in *Medtronic* v. *Lohr*, the prescription device labeling requirements contained in 21 C.F.R. section 801.109 of the Medical Device Amendments are too general to preempt a California warning statute that is a statute of general applicability directed at chemicals and not developed with respect to medical devices?

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Dr. Richard Becker, the Director of the California Office of Environmental Health Hazard Assessment ("OEHHA") and California Attorney General Daniel E. Lungren (hereinafter "State Parties") submit this opposition to the Petition for Writ of Certiorari filed by the Committee of Dental Amalgam Alloy Manufacturers and Distributors and Dentsply International Inc. (hereinafter "Dental Parties"). The Petition seeks review of a decision of the Ninth Circuit Court of Appeals holding that Proposition 65, a state "Right-to-Know" warning statute, is not preempted by the provisions of the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetics Act.

The Ninth Circuit decision is the only circuit court opinion to date discussing preemption under the MDA that has had the benefit of this Court's recent rulings in *Medtronic* v. *Lohr*, __ U.S. __, 116 S.Ct. 2240 (1996). The Ninth Circuit opinion addresses the same statute and regulations that were at issue in *Medtronic* and is absolutely consistent with this Court's opinion in that case.

OPINIONS BELOW

The opinion of the Court of Appeals for the Ninth Circuit is reported at 92 F.3d 807 (9th Cir. 1996). The opinion of the United States District Court for the Southern District of California is reported at 871 F.Supp. 1278 (S.D. Cal. 1994).

JURISDICTION

The Court of Appeals entered judgment on August 5, 1996. This Court has jurisdiction under 28 U.S.C. section 1254(1).

STATUTORY AND REGULATORY PROVISIONS

The following statutory and regulatory provisions are set forth in the Appendix to the Opposition to Petition for Writ of Certiorari ("Oppos. App."): 21 U.S.C. §§ 360(k), 360h(a), 371(a), 21 C.F.R. §§ 808.1(d), 801.109, 895.25; and California Health & Safety Code § 25249.6.

STATEMENT OF THE CASE

The Ninth Circuit's decision was issued a month after and followed directly from this Court's decision in *Medtronic* v. *Lohr*, __ U.S. __, 116 S.Ct. 2240 (1996).[1] Relying on *Medtronic*, the Ninth Circuit held that the prescription device labeling requirements contained in 21 C.F.R. section 801.109 (the same requirements at issue in *Medtronic*) were not sufficiently specific to preempt state warning requirements contained in California's Safe Drinking Water and Toxic Enforcement Act of 1986, California Health & Safety Code section 25249.5 *et seq.* ("Proposition 65"). The Ninth Circuit also ruled that Proposition 65 was a state law of general applicability not directed at medical devices and therefore not preempted; and that preemption under the MDA occurs only when the Food and Drug Administration ("FDA") has imposed a requirement, and not when the FDA has simply failed to impose a warning.

Not only was the Ninth Circuit's opinion based directly on *Medtronic*, it is the first circuit court opinion to have applied the *Medtronic* analysis to the question of preemption under the MDA.

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1. The State of California submitted a Brief Amicus Curiae to this Court in the *Medtronic* case, explaining Proposition 65 and the issues presented in this case.

A. The Relevant Statutes

1. Medical Device Amendments to the Food, Drug and Cosmetics Act

The Federal Food, Drug and Cosmetics Act ("FDCA") was enacted in order to keep interstate commerce free from deleterious, adulterated and misbranded articles of specified types. *U.S.* v. *Walsh,* 331 U.S. 432, 434 (1947). In 1976 Congress passed the Medical Device Amendments ("MDA") to the FDCA and gave the FDA the "authority to promulgate regulations for the efficient enforcement of the chapter. . ." 21 U.S.C. § 371(a).

As part of the MDA, Congress enacted an express preemption provision in 21 U.S.C. section 360k(a) which provides:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement --
>
> 1) which is different from, or in addition to any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

The implementing regulations promulgated by the FDA make clear that the MDA preempts state regulation of a medical device only when there exist specific counterpart regulations or requirements applicable to the device.

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.

21 C.F.R. § 808.1(d).

The regulations further recognize that certain state laws and regulations may affect devices but still not be preempted by the MDA:

> There are other State or local requirements that affect devices that are not preempted by section 521(a) [360(k)] of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) [360(k)] of the act.

Id. Non-preempted requirements are those of "general applicability":

> where the purpose of the requirement relates . . . to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)). . . .

21 C.F.R. § 808.1(d)(1).

Pursuant to its authority, the FDA promulgated certain general requirements that apply to all medical devices. The only requirement at issue here is the general control imposed under 21 C.F.R. section 801.109 which applies to all prescription devices and exempts them from the labeling requirements contained in 21 U.S.C. section 352(f). Section 801.109(c) states that manufacturers of prescription devices are exempt from the requirements of section 352(f) if, among other things, the device's labeling:

> bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended. . . .

At issue in this case is a medical device known as dental mercury,[2] defined in the MDA as "a device composed of mercury intended for use as a component of amalgam alloy in the restoration of a dental cavity or broken tooth." 21 C.F.R. § 872.3700. Dental mercury contains mercury, and exposes dentists and dental patients to mercury vapors.

While the FDA has absolute authority to promulgate additional specific warning requirements for medical devices or to prohibit warnings it believes to be improper, 21 U.S.C. § 371(a), 21 U.S.C. § 360h(a), 21 C.F.R. § 895.25, it has done neither with dental mercury.

2. Proposition 65

Proposition 65 is a state "Right to Know" statute, passed by the voters of California in 1986. It requires that the public be informed about exposures to certain listed chemicals that are carcinogens and/or reproductive toxins. Proposition 65 specifically states:

> No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual.

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2. The Ninth Circuit determined that dental amalgam is also regulated as a medical device in the MDA. *Committee of Dental Amalgam Alloy Manufacturers* v. *Stratton*, 92 F.3d 807, 810-11 (9th Cir. 1996).

Cal. Health & Safety Code § 25249.6.

Section 25249.10 provides that no warning is required when the person responsible can show that the exposure poses no significant risk or will have no observable effect.

Proposition 65 does not define the term warning, but explains that warnings may be provided "by general methods such as labels on consumer products, inclusion of notices in mailings to water customers, posting of notices, placing notices in public news media, and the like, provided that the warning accomplished is clear and reasonable." Health & Safety Code § 25249.11(f). The "safe harbor"[3] warning language for consumer products that contain reproductive toxins is: "**WARNING**: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm." 22 Cal. Code Reg. ("C.C.R.") § 12601(b).

Pursuant to California Health & Safety Code section 25249.7(c), the California Attorney General may sue in the name of the people of the State of California to enforce Proposition 65. In addition, private parties are authorized to enforce the provisions of the statute if they have given notice of the alleged violations to the Attorney General and the Attorney General does not file suit within sixty days after receipt of such notice. Cal. Health & Safety Code § 25249.7(d). The citizen suit

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3. Warnings that include the "safe harbor" language and employ methods of transmission set forth in the statute are deemed to be clear and reasonable. 22 Cal. Code Reg. § 12601(b).

provisions of Proposition 65 are modeled generally after a variety of federal environmental laws such as the Clean Water Act. *See* 33 U.S.C. § 1365(a)(1).

Mercury is a listed reproductive toxin under Proposition 65. 22 C.C.R. § 12601(c). The statute therefore requires that a manufacturer and/or distributor of a product that exposes individuals to mercury must provide the required warning. No warning is required if the manufacturers/distributors can show that the exposure poses no significant risk or will have no observable effect.

B. Background To This Litigation

The controversy arose in August, 1993, when the Environmental Law Foundation ("ELF"), a public interest environmental group, served citizen suit notices under Proposition 65 on Dentsply, Inc. and other manufacturers of dental mercury, notifying them that they were in violation of Proposition 65 for having failed to warn persons exposed to mercury from dental mercury used in fillings. The sixty-day notice period expired and the Attorney General did not file suit,[4] thus leaving ELF free to file its own suit seeking enforcement of Proposition 65. ELF negotiated a settlement with one manufacturer of dental mercury. The settlement required the manufacturer to provide a reproductive toxicity warning to dentists and to instruct that the warning be posted in the dental offices. Except under certain conditions, that have not arisen, the manufacturer

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4. The decision of the Attorney General not to file suit in response to a Sixty-Day Notice is not intended to be a reflection on the validity of the claim.

could continue to sell its product even if the dentists did not post the warning. A stipulated penalty was set at $328,000 but was reduced to zero and the manufacturer was instead required to pay $26,400 in attorneys' fees. *Environmental Law Foundation* v. *Jeneric-Pentron, Inc.*, No. 957039 (Cal. Super. Ct. San Francisco County, December 13, 1993) (stipulation for judgment).[5]

Before ELF could file suit, the Dental Parties sued the Attorney General of the State of California and the Director of the Office of Environmental Health Hazard Assessments ("OEHHA"), the state agency charged with drafting regulations for Proposition 65. The suit asked for declaratory relief and an injunction on the grounds that Proposition 65, as it applied to dental mercury, was preempted by the MDA. On August 24, 1994 the district court ruled that the prescription device labeling requirements of the MDA, 21 C.F.R. section 801.109, preempted the warning requirement of Proposition 65 as it applied to dental mercury and dental amalgam.

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5. Petitioners' description of the settlement (Petition at 22) is misleading. Petitioners neglected to inform the Court of the penalty reduction provision and the fact that, except under circumstances that have not yet arisen, the manufacturer can continue to sell dental mercury even if the dentists refuse to provide a warning to the dental patient.

The State Parties appealed the District Court's ruling. The Ninth Circuit, relying directly on this Court's decision in *Medtronic*, reversed the district court and held that the prescription device labeling requirements contained in 21 C.F.R. section 801.109 were not sufficiently specific to preempt state law. *Committee of Dental Amalgam Alloy Manufacturers and Distributors* v. *Stratton*, 92 F.3d 807, 812-13 (9th Cir. 1996). Again relying on this Court's decision in *Medtronic* and the regulation contained in 21 C.F.R. section 808.1(d), the Ninth Circuit also held that Proposition 65 was a state law of general applicability that was not enacted "with respect to" medical devices and therefore is not preempted by the MDA. *Dental Amalgam*, 92 F.3d at 813. Finally, the Ninth Circuit held that the FDA's failure to impose a federal reproductive toxicity warning requirement on dental mercury was not by itself preemptive. The Ninth Circuit concluded that, consistent with precedents of this Court and the decisions of numerous circuit courts, inaction by the FDA is not sufficient to trigger preemption under the MDA. *Id.*

The Ninth Circuit decision means that Proposition 65 can be enforced against the manufacturers of medical devices when the devices expose individuals to certain listed chemicals. The courts have not yet ruled on the question of whether a warning is required for dental mercury and what constitutes a clear and reasonable warning under the statute.

REASONS FOR DENYING THE WRIT

I.

THE NINTH CIRCUIT CORRECTLY DECIDED THE ISSUES IN THIS CASE BASED ON THIS COURT'S DECISION IN *MEDTRONIC*

In reaching its decision in *Dental Amalgam*, the Ninth Circuit had the benefit of this Court's decision in *Medtronic* v. *Lohr*, issued only one month prior to the Ninth Circuit decision. *Medtronic* interpreted the exact same federal preemption provision and regulations that are at issue here. The Ninth Circuit closely tracked both the reasoning and the holdings of *Medtronic* and its conclusions are consistent with this Court's opinion.

A. The *Dental Amalgam* Decision Follows this Court's Ruling in *Medtronic* that 21 C.F.R. Section 801.109 is not Sufficiently Specific to Preempt State Law Warning Requirements

At issue in the *Medtronic* case was the question of whether the prescription device labeling requirements contained in 21 C.F.R. section 801.109(b),(c) preempted state common law warning claims. 116 S.Ct. at 2256. This Court first held that:

> federal requirements must be "applicable to the device" in question, and, according to the regulations, preempt state law only if they are "specific counterpart regulations" or "specific" to a "particular device." The

> statute and regulations, therefore, require a careful comparison between the allegedly preempting federal requirement and the allegedly preempted state requirement to determine whether they fall within the intended preemptive scope of the statute and regulations.

Id. at 2257-58.

Noting that the statutory and regulatory language of the MDA does not necessarily preclude "general" federal requirements from ever preempting state requirements, 116 S.Ct. at 2257, the Court then went on to address the question of whether 21 C.F.R. section 801.109(b),(c) was a "specific counterpart regulation" that preempted state law. It concluded that it was not because it was too general:

> Such a comparison mandates a conclusion that the Lohrs' common-law claims are not preempted by the federal labeling and manufacturing requirements. The generality of those requirements make this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers. Rather, the federal

> requirements reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to protect from potentially contradictory state requirements.

Id. at 2258.

Here, the district court had determined that Proposition 65's warning requirement was preempted by the prescription device labeling requirement contained in 21 C.F.R. section 801.109. The Ninth Circuit quoted the above section of the *Medtronic* opinion and reversed the district court, holding that the prescription device labeling requirements were not "specific" enough to preempt state law. *Dental Amalgam*, 92 F.3d at 813.

The Dental Parties are therefore wrong when they assert that the Ninth Circuit has imposed a test for preemption that contradicts this Court's rulings and requires that a federal provision must apply exclusively to one type of medical device in order to preempt state law. (Petition at 18) The Ninth Circuit simply reiterated the direct holding of this Court concerning the preemptive effect of one particular federal requirement (21 C.F.R. section 801.109), and applied it to the facts of this case, holding that the same prescription device labeling requirements found by this Court to be too general to preempt state common law warning claims, were also too general to preempt a state law statutory warning requirement.

B. The *Dental Amalgam* Decision Follows This Court's Ruling in *Medtronic* that Certain State Laws of General Applicability are Not Preempted

Relying on the regulation contained in 21 C.F.R. section 808.1(d), this Court concluded that, while the statutory and regulatory language does not necessarily preclude general state requirements from ever being preempted, the state common law claims in *Medtronic* were not specifically developed "with respect to" medical devices and were not the kinds of requirements that Congress and the FDA intended to preempt. The Court went on to note that the common law claims, which included the failure to warn, were "no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a workforce." *Medtronic*, 116 S.Ct. at 2258.

Relying on *Medtronic*, the Ninth Circuit performed the "careful comparison between the allegedly preempting federal requirement and the allegedly preempted state requirement" (*Medtronic*, 116 S.Ct. at 2257-58) and concluded that Proposition 65, was not enacted "with respect to" medical devices and was not the kind of requirement that Congress and the FDA intended to preempt. Rather, Proposition 65 was directed at chemicals known to pose a health risk, and the state of California had not adopted any specific regulation or requirement that related to dental mercury or to the medical device industry. The court concluded therefore, that Proposition 65 was a statute of general applicability and was not preempted by the MDA because it was not the kind of requirement "that

Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements." *Dental Amalgam*, 92 F.3d at 813 (quoting *Medtronic*, 116 S.Ct. at 2257). The Ninth Circuit ruling therefore follows directly from and is consistent with *Medtronic*.

C. The *Dental Amalgam* Decision is Consistent with General Precedents of this Court and with the Decisions of Other Circuit Courts Holding that the FDA Cannot Preempt by Inaction

The Dental Parties next assert that this Court should grant the petition for writ of certiorari to address the question of whether the FDA can regulate by inaction -- *i.e.*, whether the FDA's failure to impose a requirement can preempt state law.[6]

The general question of when regulation can be inferred from inaction has already been answered by this Court. In *Puerto Rico Consumer Affairs Dept.* v. *Isla Petroleum Corp.*, 485 U.S. 495, 503 (1988) this Court held

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6. In presenting this question to the Court, petitioner represents that the FDA has "affirmatively rejected" a reproductive toxicity warning for dental mercury (Petition at 23). There is nothing in the record that demonstrates that the FDA has specifically considered and affirmatively rejected a reproductive toxicity warning for dental mercury. Furthermore, it is absolutely undisputed that the FDA has never promulgated a regulation prohibiting such a warning.

that "[t]here is no federal preemption *in vacuo*, without a constitutional text or a federal statute to assert it."

The federal statute and the regulations here make clear that Congress and the FDA did not anticipate regulation by inaction. The language of the preemption provision of the MDA states that preemption occurs only when there exists a "requirement applicable under this chapter to the device. . . . " 21 U.S.C. § 360k(a). In promulgating the regulation set forth in 21 C.F.R. section 808.1(d), the FDA specifically considered and rejected public comments arguing that, if no FDA requirement exists, any state requirement is "in addition to" an FDA requirement and is therefore preempted. 43 Fed.Reg. 19662 (1978). The FDA noted that "from a plain reading of section 521 of the act [360k] ***it is clear that the scope of preemption is limited to instances where there are specific FDA requirements applicable to a particular device or class of devices.***" *Id.* (Emphasis added.) The FDA went on to state unambiguously that:

> The language of section 521 of the act [360k] also does not support the argument that any State or local requirement is "in addition to" an FDA requirement if there is no FDA requirement. ***The phrase "or in addition to, any requirement applicable under this Act to the device" means that an FDA requirement must exist before preemption can occur.***

Id. (Emphasis added).

Discussion by the Commissioner of the FDA indicates further that the FDA does not intend to preempt by inaction. "Congress intended section 521(a) [360k] of the act to preempt only those different or

additional State and local requirements that relate to matters already governed by specific, established Federal requirements applicable to a specific device." 42 Fed.Reg. 9186 (Feb. 16, 1977). In a later discussion, the FDA provided a concrete example of the manner in which it envisioned preemption applying.

> For example, as noted in the recent regulation relating to professional and patient labeling and conditions for sale of hearing aids, State or local requirements that relate to such labeling requirements or conditions for sale *will be preempted by section 521(a) on the effective date of the hearing aid regulation. . . .*

42 Fed.Reg. 30384 (emphasis added). In other words, according to the FDA, until it acted to impose specific regulations on hearing aids, state regulation was not preempted.

Case law is unanimous in supporting the FDA's interpretation that preemption does not occur because of the agency's inaction. *See e.g.*, *King* v. *Collagen Corp.*, 983 F.2d 1130, 1134 (1st Cir. 1993), *cert. denied*, 510 U.S. 824 (1993) ("FDA regulations provide that preemption does not apply when the FDA has issued no regulations or other requirements specific to the particular device."); *Moore* v. *Kimberly-Clark Corp.*, 867 F.2d 243, 245 (5th Cir. 1989) (FDA requirement must exist before preemption occurs); *Lamontagne* v. *E. I. Du Pont de Nemours & Co.*, 834 F.Supp. 576, 585-86 (D.Conn. 1993), *aff'd.* 41 F.3d 846, 855 (2d Cir. 1994), (rejecting the

argument that state regulation was preempted because the FDA has chosen not to regulate).[7]

In *National Bank of Commerce* v. *Kimberly-Clark*, 38 F.3d 988, 997 (8th Cir. 1994) the tampon manufacturer defendant argued that, because the FDA had considered and rejected broader regulation of tampons, that decision by the FDA not to regulate preempted the plaintiff's claims. As noted by the court:

> Such a holding is precluded by the FDA's own regulations, but in addition, it would evince total disregard for the structure of our federal system. Absent clear statutory language to the contrary (or ambiguous statutory language accompanied by a reasonable agency interpretation to the contrary) it would be anomalous to suggest that the FDA may preempt all possible tort actions involving a particular product simply by placing it into a class or by imposing some general control.

Id.

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7. In *Lamontagne*, the court was faced with a regulation stating expressly that the FDA would not regulate manufacturers of raw materials because such regulation was not necessary to protect the public health. *See* 21 C.F.R. § 807.65. Despite this express determination, the court still found that the FDA refusal to regulate was not sufficient to preempt state law. *Lamontagne*, 834 F.Supp. at 585.

Thus, the Ninth Circuit decision here, refusing to find preemption by inaction, is consistent with the guidance provided by this Court in *Isla Petroleum* as well as with the decisions of the First, Second, Fifth and Eighth Circuits.

II.

THE *DENTAL AMALGAM* DECISION DOES NOT CONFLICT WITH THE DECISIONS IN OTHER CIRCUITS

In urging this Court to grant the petition for writ of certiorari, the Dental Parties assert that the standard for preemption in the Ninth Circuit conflicts with the standards in other circuits. The case law demonstrates however, that any conflicts exist only with cases that predate *Medtronic* and are therefore no longer necessarily good law.

This Court has provided significant guidance in *Medtronic* concerning preemption under the MDA. Apart from the Ninth Circuit, no other circuit court has had the opportunity to apply that guidance in the context of cases raising questions of preemption under the MDA. Thus, there is no conflict. Until a conflict arises, there is no reason for this Court to address issues that may well be resolved consistently at the circuit court level.

A. The *Dental Amalgam* Opinion is the Only Post-*Medtronic* Decision to Address the Question of Whether the Federal Prescription Device Labeling Requirements Preempt State Law

In its decision here, the Ninth Circuit, relying directly on *Medtronic*, ruled that the prescription device labeling requirements contained in 21 C.F.R. section 801.109 were not sufficiently specific to preempt Proposition 65's warning requirements. *Dental Amalgam*, 92 F.3d at 813.

Other than *Dental Amalgam*, there are no post-*Medtronic* cases that have dealt with the preemptive effect of these same requirements.[8] The only "conflict" asserted by the Dental Parties is based, not on the *Dental Amalgam* decision, not on the regulations contained in section 801.109 and not on a state statutory warning requirement, but rather on Ninth Circuit opinions in entirely different and earlier cases. One of those decisions, *Kennedy* v. *Collagen Corp.*, 67 F.3d 1453, 1458 (9th Cir. 1995) *cert. denied*, 116 S.Ct. 2579 (1996), dealt with the federal pre-market approval ("PMA") requirements (21 C.F.R. § 814.1) and their preemptive effect on state common law claims. The Kennedy court held that the PMA requirements did not preempt state law because they were not a "specific requirement applicable to a particular device." 67 F.3d at 1459. The Dental Parties claim that this reasoning conflicts with the decisions of the First, Third, Fifth and Eighth Circuits which have found that the PMA requirements are

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8. There are several earlier decisions that found that 21 CFR section 801.109 did preempt state common law warning claims. *See, e.g.*, *Mendes* v. *Medtronic*, 18 F.3d 13, 18 (1st Cir. 1994); *Reeves* v. *Acromed Corp.*, 44 F.3d 300, 305 (5th Cir.), *cert. denied*, 115 S.Ct. 2251 (1995). None of these cases is good law after this Court's decision in *Medtronic*.

sufficiently specific to preempt state common law. (Petition at 19).

Whether a conflict exists or not, it exists in an entirely different, pre-*Medtronic* case, dealing with a different federal requirement, and different state requirements.[9] The question whether a specific federal requirement preempts state law must be addressed on a case by case basis by comparing the federal and state requirements at issue, *Medtronic*, 116 S.Ct. at 2257-58. The *Dental Amalgam* case, involving a device that did not go through the pre-market approval process, is simply not an appropriate vehicle with which to address the questions raised by *Kennedy*.[10]

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9. The second decision on which the Dental Parties based their conflict argument is *Anguiano* v. *E.I. DuPont de Nemours & Co.*, 44 F.3d 806, (9th Cir. 1995). *Anguiano*, however, is consistent with this Court's ruling in *Medtronic*. In *Anguiano*, the device at issue, a temporomandibular joint (TMJ), was subject only to the identification and classification regulations that are used to classify all medical devices. While the court did not discuss the prescription device labeling requirements contained in 21 C.F.R. section 801.109, those are the only labeling requirements that would have been applicable to the TMJ. Thus, the Ninth Circuit's ruling in *Anguiano*, 44 F.3d at 809-10, that the federal requirements were not sufficiently specific to preempt state common law claims, is consistent with the *Medtronic* opinion.

10. Furthermore, this Court denied certiorari in *Kennedy* only days after it decided *Medtronic*. It simultaneously vacated and remanded at least one circuit court decision that raises the exact question presented by

B. The Ninth Circuit is the Only Circuit Court to Have Addressed the Question of Whether a State Statute is of General Applicability and Therefore Not Preempted by the MDA

In *Medtronic*, this Court provided significant guidance concerning when state requirements are requirements of general applicability, not specifically developed with respect to medical devices and therefore not preempted. The Court has made clear that certain general state requirements are not the kinds of requirements that Congress and the FDA feared would impede the federal regulators from enforcing federal requirements and are therefore not a threat to federal requirements. 116 S.Ct. at 2258.

The *Dental Amalgam* opinion is the only case to date to have applied the *Medtronic* guidance in determining that a state requirement is of general applicability and is not intended to be preempted by federal law. This decision cannot conflict with any of the cases cited by the Dental Parties, all of which predate *Medtronic* and all of which deal with state common law requirements.[11/]

Kennedy, i.e., whether the PMA process is a specific requirement that preempts state common law claims. *See Mitchell* v. *Collagen Corp.*, 67 F.3d 1268, 1279 (7th Cir. 1995), *vacated and remanded* 116 S.Ct. 2576 (1996). If the *Mitchell* decision on remand continues to presents a direct conflict with *Kennedy*, the Court will have an appropriate vehicle in which to resolve that conflict.

11. *See Michael* v. *Shiley, Inc.*, 46 F.3d 1316 (3d Cir.), *cert. denied*, 116 S.Ct. 67 (1995); *Gile* v. *Optical*

Recognizing the absence of a direct conflict, the Dental Parties again shift the focus of their argument from the *Dental Amalgam* decision to the *Kennedy* decision. (Petition at 15) The pre-*Medtronic Kennedy* opinion dealt with preemption of common law tort claims and concluded that, if a state common law requirement is not specifically directed at medical devices, but affects such devices in the same manner as it affects all other products, it is not preempted. *Kennedy*, 67 F.3d at 1462. While the Ninth Circuit *Kennedy* opinion did conflict with pre-*Medtronic* decisions in other circuits, *see* 67 F.3d at 1461, n.3 (Reinhardt, J. concurring), it is consistent with this Court's decision in *Medtronic* that the particular common law claims at issue were not specifically developed "with respect to" medical devices and were therefore not preempted. 116 S.Ct. at 2258. Furthermore, this Court specifically chose to address any existing conflict by denying certiorari in *Kennedy* (116 S.Ct. 2579), and vacating and remanding a number of decisions that presented a potential conflict with *Kennedy*.[12/]

Radiation Corp., 22 F.3d 540, 543 n.2 (3d Cir.), *cert. denied*, 115 S.Ct. 429 (1994); *Talbott* v. *C.R. Bard, Inc.*, 63 F.3d 25, 29 (1st Cir. 1995), *cert. dismissed*, 116 S.Ct. 1892 (1996); *Becker* v. *Optical Radiation Corp.*, 66 F.3d 18, 20 n.2, 20-21 (2d Cir. 1995); *Stamps* v. *Collagen Corp.*, 984 F.2d 1416, 1421 (5th Cir.), *cert. denied*, 510 U.S. 824 (1993); *Slater* v. *Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), *cert. denied*, 505 U.S. 917 (1992); *Martello* v. *Ciba Vision Corp.*, 42 F.3d 1167, 1169 (8th Cir. 1994); *Duncan* v. *Iolab Corp.*, 12 F.3d 194 (11th Cir. 1994).

12. *English* v. *Mentor Corp.*, 67 F.3d 477 (3d Cir. 1995), *vacated and remanded*, 116 S.Ct. 2575 (1996);

Thus, any conflict in the law concerning preemption of common law tort claims exists not in the *Dental Amalgam* decision, but in other, pre-*Medtronic* decisions and should be resolved only after the circuit courts have had an opportunity to reevaluate their positions in light of this Court's ruling in *Medtronic*. Since the Court has remanded a number of circuit court decisions for further considerations in light of *Medtronic*, it will have ample opportunity to resolve any conflicts that remain. Furthermore, consistent with this Court's ruling that preemption analysis demands a careful comparison between the federal and state requirements at issue, 116 S.Ct. at 2257-58, any conflicts concerning preemption of particular common law claims can only be resolved in the context of cases raising the same or similar common law claims. The *Dental Amalgam* case is simply not an appropriate vehicle in which to resolve these conflicts.

In summary, this Court has now provided significant guidance concerning the preemption of state law requirements. That guidance was specifically applied to the facts of this case by the Ninth Circuit and will be applied to different facts by different circuits. Until the

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Duvall v. *Bristol-Myers Squibb Co.*, 65 F.3d 392 (4th Cir. 1995), *vacated and remanded*, 116 S.Ct. 2575 (1996); *Bingham* v. *Mentor Corp.*, 89 F.3d 203 (5th Cir.), *vacated and remanded*, 116 S.Ct. 2577 (1996); *Feldt* v. *Mentor Corp.*, 61 F.3d 431 (5th Cir. 1995), *vacated and remanded*, 116 S.Ct. 2575 (1996); *Martin* v. *Telectronics Pacing Sys., Inc.*, 70 F.3d 39 (6th Cir. 1995), *vacated and remanded*, 116 S.Ct. 2576 (1996); *Mitchell* v. *Collagen Corp.*, 67 F.3d 1268 (7th Cir. 1995), *vacated and remanded*, 116 S.Ct. 2576 (1996).

circuit courts have had an opportunity to consider and apply the *Medtronic* decision to their own cases, there is no conflict for this Court to resolve.

III.

THE SCOPE OF FDA AUTHORITY UNDER THE MDA IS WELL DEFINED AND THERE IS NO NEED FOR THIS COURT TO ADDRESS THE EXTENT OF THAT AUTHORITY

In a final argument, the Dental Parties attempt to present the Court with a question they term one of "federalism" -- whether the FDA can regulate by inaction -- and suggest that the Court grant certiorari in order to define the relationship between state and federal power over medical devices. The question of FDA regulation by inaction, however, does not raise an issue of federalism, but rather one of statutory interpretation. "There is no federal preemption *in vacuo*, without a constitutional text or a federal statute to assert it." *Isla Petroleum*, 485 U.S. at 503.

Here, the scope of the FDA's authority to regulate is clear from the statute and, pursuant to 21 U.S.C. sections 360h(a) and 371(a) and 21 C.F.R. section 895.25, the FDA has the absolute authority to promulgate a regulation prohibiting the use of a reproductive toxicity warning for dental mercury. It has not done so. Furthermore, the language of the MDA, the provisions of the regulations and the comments of the FDA make clear that neither Congress nor the FDA intends that the Agency regulate by inaction. *See* 21 U.S.C. § 360k(a), 21 C.F.R. § 808.1(d), 43 Fed. Reg. 19662, 42 Fed. Reg. 9186, 42 Fed. Reg. 30384. *See also King*, 983 F.2d at 1130; *Moore*, 867 F.2d at 245;

Lamontagne, 834 F.Supp. at 585-86, *aff'd.* 41 F.3d at 855; *National Bank of Commerce*, 38 F.3d at 997.

Finally, contrary to the representations of the Dental Parties, the *Dental Amalgam* decision, permitting the State to seek to enforce a warning requirement even though federal law does not impose the requirement is neither unusual nor extraordinary. It is precisely what the preemption provisions of the MDA anticipate. *See Medtronic*, 116 S.Ct. at 2256-57 (permitting state common law failure to warn and negligent manufacturing claims.

Nor is it unusual that the Proposition 65 warning requirement may be enforced pursuant to a citizen suit. Citizen suit provisions are a staple of federal statutes and have long been recognized as a legitimate enforcement mechanism in federal law. *See* Clean Water Act 33 U.S.C. § 1365(a)(1).[13]

Finally, in an argument never addressed to the courts below, the Dental Parties represent that the warning requirement of Proposition 65 violates federal law. (Petition at 26) This argument is not only improper because it was not raised below, it is absolutely incorrect. In making this claim, the Dental Parties quote from a report of the Department of Health and Human Services, stating that the FDA could take action to prevent individual dentists from claiming that dental amalgams are toxic to humans or causative agents for

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13. While Petitioners are correct that the Attorney General has criticized certain citizen suits brought by irresponsible private groups, he has never indicated that he believed that the Environmental Law Foundation fell into that category.

diseases. *Dental Amalgam: A Scientific Review* at VI-5 ("*Dental Amalgam Report*") (Petition at 26). The report, "A Scientific Review and Recommended Public Health Strategy for Research, Education and Regulation," was directed at the alleged practice of certain dentists in promoting amalgam removal and replacement by other materials. The *Dental Amalgam Report*, however, can hardly be taken as an indication that a Proposition 65 warning is illegal under federal law. First, the report was issued by the United States Department of Health and Human Services, not by the FDA and is not a definitive statement of the scope of FDA authority. Second, the Report, in the next sentence not quoted by the Dental Parties, goes on to indicate that any question of improper activity by dentists is better handled by the states through licensing and regulating bodies, rather than by the FDA. Third, the FDA has always recognized that "mercury is a poison," 52 Fed.Reg. 30089, and fourth, and finally, while the FDA has the authority to prohibit a reproductive toxicity warning, it has not done so. Thus, federal law simply does not prohibit either manufacturers of dental mercury or dentists from providing an appropriate Proposition 65 warning pursuant to state law.

CONCLUSION

In the *Medtronic* decision, this Court has provided significant clarification to an area of law that was in considerable disarray. The *Medtronic* decision addressed the same statute and the same federal requirements that are at issue here. The Ninth Circuit, which simply followed this Court's reasoning and conclusions, is the first circuit court to apply the *Medtronic* reasoning to the facts of a specific case and to perform the careful comparison between federal and

state requirements that is mandated by this Court. Until other circuit courts have had the same opportunity to apply *Medtronic*, there is no conflict that justifies this Court granting the petition for writ of certiorari.

The Court should deny the petition for writ of certiorari.

Respectfully submitted,

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December 4, 1996.

APPENDIX TO THE OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

implementing regulations included any requirement concerning the advertising of hearing aids, West's Ann. Health & Safety Code, § 26463(m) making it unlawful for any person to advertise any device represented to have any effect on diseases or disorders of the ear or auditory apparatus, including hearing loss, was not preempted by federal law. Kievlan v. Dahlberg Electronics, Cal.App. 1 Dist.1978, 144 Cal.Rptr. 585, 78 Cal.App.3d 961, appeal dismissed 99 S.Ct. 1487, 440 U.S. 951, 59 L.Ed.2d 765.

3. Restrictive devices

In establishing what medical devices are "restrictive devices" under this section, the Secretary is not forbidden from using language approaching the generality of this section if, after appropriate rule-making procedures, he should find it impracticable to be more specific, and it was not intended that he make specific determinations with respect to each device, with the consequence that a new device would not be "restricted" until a special rule had been developed for it. Becton, Dickinson and Co. v. Food and Drug Administration, C.A.2 (N.Y.) 1978, 589 F.2d 1175.

Notice published by the Secretary in the federal register stating that "restricted devices" now include all "prescription devices" as defined in previously promulgated regulations was not sufficient regulation under this section to satisfy requirement that the Secretary may by regulation require that a device be restricted in sale, distribution or use if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness. Becton, Dickinson and Co. v. Food and Drug Administration, C.A.2 (N.Y.) 1978, 589 F.2d 1175.

Medical Device Amendments (MDA) to Food, Drug & Cosmetic Act did not preempt state law causes of action based upon strict liability, negligence, and breach of implied warranty, of individual allegedly injured by defective prosthetic knee device, as those causes of action were requirements of general applicability rather than state laws enacted specifically with regard to "device intended for human use," and state law liability was specifically contemplated by MDA. Mulligan v. Pfizer Inc., S.D.Ohio 1994, 850 F.Supp. 633.

4. Mandatory nature of section

Subsec. (h)(2) of this section establishing scheme under which Administration was required to make available to public "a detailed summary of information respecting the safety and effectiveness of a device which information was submitted to the [agency] and which was the basis for" specified orders or was submitted to advisory committee and formed basis for its recommendations to Administration did not specifically prohibit disclosure of records produced during ongoing clinical studies of safety and efficacy of intraocular lenses as required under exemption provisions of section 552(b)(3) of Title 5 allowing agencies to withhold records that are "specifically exempted from disclosure by statute." Public Citizen Health Research Group v. Food and Drug Admin., C.A.D.C.1983, 704 F.2d 1280, 227 U.S.App.D.C. 151.

5. Custom device

Food and Drug Administration acted reasonably in refusing to accord "custom-device" status to rigid gas permeable contact lenses within meaning of statute [21 U.S.C.A. § 360j(b)] which provides exemption for custom devices from classification scheme of Medical Device Amendments of 1976 [21 U.S.C.A. §§ 360c–360k]. Contact Lens Mfrs. Ass'n v. Food & Drug Admin. Dept. of Health and Human Services, C.A.D.C.1985, 766 F.2d 592, 247 U.S.App.D.C. 102, certiorari denied 106 S.Ct. 810, 474 U.S. 1062, 88 L.Ed.2d 784.

6. Good manufacturing practice

Manufacturer of latex surgical gloves violated finished device testing requirements of good manufacturing practice regulations under Federal Food, Drug, and Cosmetic Act by failing to adhere to any recognized glove testing standard. U.S. v. 789 Cases, More or Less, of Latex Surgeons' Gloves, an Article of Device, D.Puerto Rico 1992, 799 F.Supp. 1275.

Compliance office of division of compliance programs of Food and Drug Administration could not bypass process for establishing good manufacturing practice and was required to comply with process in order to require manufacturers of plated culture media to meet sterility assurance level of 0.1%. U.S. v. Bioclinical Systems, Inc., D.Md.1987, 666 F.Supp. 82.

§ 360k. State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such

regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

(June 25, 1938, c. 675, § 521, as added May 28, 1976, Pub.L. 94-295, § 2, 90 Stat. 574.)

HISTORICAL AND STATUTORY NOTES

Change of Name

The Department of Health, Education, and Welfare was redesignated the Department of Health and Human Services, and the Secretary of Health, Education, and Welfare or any other official of the Department of Health, Education and Welfare was redesignated the Secretary or official, as appropriate, of Health and Human Services, with any reference to the Department of Health, Education, and Welfare, the Secretary of Health, Education, and Welfare, or any official of the Department of Health, Education, and Welfare, in any law, rule, regulation, certificate, directive, instruction, or other official paper in force on the effective date of Pub.L. 96-88, as prescribed by section 601 of Pub.L. 96-88, Title VI, Oct. 17, 1979, 93 Stat. 696, set out as a note under section 3401 of Title 20, Education, deemed to refer and apply to the Department of Health and Human Services or the Secretary of Health and Human Services, respectively, except to the extent such reference is to a function or office transferred to the Secretary of Education or the Department of Education under Pub.L. 96-88, Title III, §§ 301 to 307, Oct. 17, 1979, 93 Stat. 677 to 681. See section 3441 to 3447 and 3508 of Title 20.

Legislative History

For legislative history and purpose of Pub.L. 94-295, see 1976 U.S. Code Cong. and Adm. News, p. 1070.

CODE OF FEDERAL REGULATIONS

Exemption from federal preemption, see 21 CFR 808.1 et seq.

LAW REVIEW COMMENTARIES

Preemption of state tort claims under the medical device amendments. Stephen D. Harris, 24 Colo.Law. 2217 (1996).

Who should bear the burden of experimental medical device testing: The preemptive scope of the medical device amendments under *Slater v. Optical Radiation Corp.* 43 DePaul L.Rev. 963 (1994).

LIBRARY REFERENCES

Food ⇐1 et seq.
C.J.S. Food § 4(1) et seq.

NOTES OF DECISIONS

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1. Requirement applicable to the device

Preemption of state requirements for products by Medical Device Amendments to Food, Drug and Cosmetic Act occurs when either general or specific requirements of Amendments apply to product. English v. Mentor Corp., C.A.3 (Pa.) 1995, 67 F.3d 477, petition for certiorari filed.

Good manufacturing practice requirements applicable to penile implant, which was Class III medical device under Medical Device Amendments to Federal Food, Drug, and Cosmetic Act (MDA), which included standards for production facilities, quality assurance, monitoring of package labels, and device failure reporting requirements, and labeling requirements, which mandated content of labels and prominence of required statements, were "requirements" and give rise to preemption under MDA of state law claims based on failure to comply with requirements. Duvall v. Bristol-Myers-Squibb Co., C.A.4 (Md.) 1996, 65 F.3d 392, petition for certiorari filed.

Food and Drug Administration (FDA) regulation providing that state and local requirements for medical devices were preempted by Medical Device Amendments (MDA) only when FDA has established specific counterpart regulations or there were other specific regulations applicable to particular device under FDA. did not limit preemption to cases of regulations covering specific device; preemption could be found if regulations covered particular process, procedure or device. Lohr v. Medtronic, Inc., C.A.11 (Fla.) 1996, 56 F.3d 1335, rehearing and suggestion for rehearing en banc denied, certiorari granted.

(f) Statement of reasons

To facilitate judicial review under this section or under any other provision of law of a regulation or order issued under section 360c, 360d, 360e, 360f, 360h, 360i, 360j, or 360k of this title each such regulation or order shall contain a statement of the reasons for its issuance and the basis, in the record of the proceedings held in connection with its issuance, for its issuance.

(June 25, 1938, c. 675, § 517, as added May 28, 1976, Pub.L. 94-295, § 2, 90 Stat. 560, and amended Nov. 28, 1990, Pub.L. 101-629, § 13, 104 Stat. 4524; June 16, 1992, Pub.L. 102-300, § 6(f), 106 Stat. 240.)

HISTORICAL AND STATUTORY NOTES

1992 Amendments

Subsec. (a)(10). Pub.L. 102-300, § 6(f), substituted "section 360j(h)(4)(B)" for "section 360j(c)(4)(B)".

1990 Amendment

Subsec. (a)(8)-(10). Pub.L. 101-629, § 13, added pars. (8) to (10).

Change of Name

The Department of Health, Education, and Welfare was redesignated the Department of Health and Human Services, and the Secretary of Health, Education, and Welfare or any other official of the Department of Health, Education and Welfare was redesignated the Secretary or official, as appropriate, of Health and Human Services, with any reference to the Department of Health, Education, and Welfare, the Secretary of Health, Education, and Welfare, or any official of the Department of Health, Education, and Welfare, in any law, rule, regulation, certificate, directive, instruction, or other official paper in force on the effective date of Pub.L. 96-88, as prescribed by section 601 of Pub.L. 96-88, Title VI, Oct. 17, 1979, 93 Stat. 696, set out as a note under section 3401 of Title 20, Education, deemed to refer and apply to the Department of Health and Human Services or the Secretary of Health and Human Services, respectively, except to the extent such reference is to a function or office transferred to the Secretary of Education or the Department of Education under Pub.L. 96-88, Title III, §§ 301 to 307, Oct. 17, 1979, 93 Stat. 677 to 681. See section 3441 to 3447 and 3508 of Title 20.

Legislative History

For legislative history and purpose of Pub.L. 94-295, see 1976 U.S. Code Cong. and Adm. News, p. 1070. See, also, Pub.L. 101-629, 1990 U.S. Code Cong. and Adm. News, p. 6305.

LIBRARY REFERENCES

Food ⇐22.
C.J.S. Food § 48.

§ 360h. Notification and other remedies

(a) Notification

If the Secretary determines that—

(1) a device intended for human use which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health, and

(2) notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this chapter (other than this section) to eliminate such risk,

the Secretary may issue such order as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all health professionals who prescribe or use the device and to any other person (including manufacturers, importers, distributors, retailers, and device users) who should properly receive such notification in order to eliminate such risk. An order under this subsection shall require that the individuals subject to the risk with respect to which the order is to be issued be included in the persons to be notified of the risk unless the Secretary determines that notice to such individuals would present a greater danger to the health of such individuals than no such notification. If the Secretary makes such a determination with respect to such individuals, the order shall require that the health professionals who prescribe or use the device provide for the notification of the individuals whom the health professionals treated with the device of the risk presented by the device and of any action which may be taken by or on behalf of such individuals to eliminate or reduce such risk. Before issuing an order under this subsection, the Secretary shall consult with the persons who are to give notice under the order.

Department of Agriculture to the Federal Security Agency, to be administered under the direction and supervision of the Federal Security Administrator, by 1940 Reorg.Plan No. IV, set out in the Appendix to Title 5.

§ 364. Repealed. Pub.L. 86-618, Title I, § 103(a) (3), July 12, 1960, 74 Stat. 398

Historical Note

Section, Act June 25, 1938, c. 675, § 604, 52 Stat. 1055, required the Secretary to promulgate regulations for the listing of coal-tar colors for cosmetics and is covered by section 376 of this title.

Effective Date of Repeal. Repeal of section effective, subject to the provisions of section 208 of Pub.L. 86-618, on July 12, 1960, see section 202 of Pub.L. 86-618, set out as a note under section 376 of this title.

SUBCHAPTER VII—GENERAL ADMINISTRATIVE PROVISIONS

§ 371. Regulations and hearings—Authority to promulgate regulations

(a) The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary.

Regulations for imports and exports

(b) The Secretary of the Treasury and the Secretary of Health, Education, and Welfare shall jointly prescribe regulations for the efficient enforcement of the provisions of section 381 of this title, except as otherwise provided therein. Such regulations shall be promulgated in such manner and take effect at such time, after due notice, as the Secretary of Health, Education, and Welfare shall determine.

Conduct of hearings

(c) Hearings authorized or required by this chapter shall be conducted by the Secretary of Health, Education, and Welfare or such officer or employee as he may designate for the purpose.

Effectiveness of definitions and standards of identity

(d) The definitions and standards of identity promulgated in accordance with the provisions of this chapter shall be effective for the purposes of the enforcement of this chapter, notwithstanding such definitions and standards as may be contained in other laws of the United States and regulations promulgated thereunder.

Procedure for establishment

(e) (1) Any action for the issuance, amendment, or repeal of any regulation under section 341, 343(j), 344(a), 346, 351(b), or 352(d) or

(2) That the requirement is required by compelling local conditions and compliance with the requirement would not cause the device to be in violation of any applicable requirement under the act.

(d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

(2) Section 521(a) does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.

(3) Section 521(a) does not preempt State or local permits, licensing, registration, certification, or other requirements relating to the approval or sanction of the practice of medicine, dentistry, optometry, pharmacy, nursing, podiatry, or any other of the healing arts or allied medical sciences or related professions or occupations that administer, dispense, or sell devices. However, regulations issued under section 520(e) or (g) of the act may impose restrictions on the sale, distribution, or use of a device beyond those prescribed in State or local requirements. If there is a conflict between such restrictions and State or local requirements, the Federal regulations shall prevail.

(4) Section 521(a) does not preempt specifications in contracts entered into by States or localities for procurement of devices.

(5) Section 521(a) does not preempt criteria for payment of State or local obligations under Medicaid and similar Federal, State or local health-care programs.

(6)(i) Section 521(a) does not preempt State or local requirements respecting general enforcement, e.g., requirements that State inspection be permitted of factory records concerning all devices, registration, and licensing requirements for manufacturers and others, and prohibition of manufacture of devices in unlicensed establishments. However, Federal regulations issued under sections 519 and 520(f) of the act may impose requirements for records and reports and good manufacturing practices beyond those prescribed in State or local requirements. If there is a conflict between such regulations and State or local requirements, the Federal regulations shall prevail.

(ii) Generally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices. Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, then the prohibition will be preempted if the requirement is different from, or in addition to, a Federal requirement established under the act. In determining whether such a requirement is preempted, the determinative factor is how the requirement is interpreted and enforced by the State or local government and not the literal language of the statute, which may be identical to a provision in the act.

(7) Section 521(a) does not preempt State or local provisions respecting delegations of authority and related administrative matters relating to devices.

(8) Section 521(a) does not preempt a State or local requirement whose sole purpose is raising revenue or charging fees for services, registration, or regulatory programs.

(9) Section 521(a) does not preempt State or local requirements of the types that have been developed under the Atomic Energy act of 1954 (42 U.S.C. 2011 note), as amended, the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602 (42 U.S.C. 263b et seq.)) and other Federal statutes, until such time as the Food and Drug Administration issues specific requirements under the Federal Food, Drug, and Cosmetic Act applicable to these types of devices.

(e) It is the responsibility of the Food and Drug Administration, subject to review by Federal courts, to determine whether a State or local requirement is equal to, or substantially identical to, requirements imposed by or under the act, or is different from, or in addition to, such requirements, in accordance with the procedures provided by this part. However, it is the responsibility of States and political subdivisions to determine initially whether to seek exemptions from preemption. Any State or political subdivision whose requirements relating to devices are preempted by section 521(a) may petition the Commissioner of Food and Drugs for exemption from preemption, in accordance with the procedures provided by this part.

(f) The Federal requirement with respect to a device applies whether or not a corresponding State or local requirement is preempted or exempted from preemption. As a result, if a State or local requirement that the Food and Drug Administration has exempted from preemption is not as broad in its application as the Federal requirement, the Federal requirement applies to all circumstances not covered by the State or local requirement.

[43 FR 18665, May 2, 1978, as amended at 45 FR 67336, Oct. 10, 1980]

§ 808.3 Definitions.

(a) *Act* means the Federal Food, Drug, and Cosmetic Act.

(b) *Compelling local conditions* includes any factors, considerations, or circumstances prevailing in, or characteristic of, the geographic area or population of the State or political subdivision that justify exemption from preemption.

(c) *More stringent* refers to a requirement of greater restrictiveness or one that is expected to afford to those who may be exposed to a risk of injury from a device a higher degree of protection than is afforded by a requirement applicable to the device under the act.

(d) *Political subdivision* or *locality* means any lawfully established local governmental unit within a State which unit has the authority to establish or continue in effect any requirement having the force and effect of law with respect to a device intended for human use.

(e) *State* means a State, American Samoa, the Canal Zone, the Commonwealth of Puerto Rico, the District of Columbia, Guam, Johnston Island, Kingman Reef, Midway Island, the Trust Territory of the Pacific Islands, the Virgin Islands, and Wake Island.

(f) *Substantially identical to* refers to the fact that a State or local requirement does not significantly differ in effect from a Federal requirement.

§ 808.5 Advisory opinions.

(a) Any State, political subdivision; or other interested person may request an advisory opinion from the Commissioner with respect to any general matter concerning preemption of State or local device requirements or with respect to whether the Food and Drug Administration regards particular State or local requirements, or proposed requirements, as preempted.

(1) Such an advisory opinion may be requested and may be granted in accordance with § 10.85 of this chapter.

(2) The Food and Drug Administration, in its discretion and after consultation with the State or political subdivision, may treat a request by a State or political subdivision for an advisory opinion as an application for exemption from preemption under § 808.20.

(b) The Commissioner may issue an advisory opinion relating to a State or local requirement on his own initiative when he makes one of the following determinations:

(1) A requirement with respect to a device for which an application for exemption from preemption has been submitted under § 808.20 is not preempted by section 521(a) of the act because it

practice or by unavoidable deviations in good manufacturing practice will be recognized. Variations from stated quantity of contents shall not be unreasonably large.

Subpart D—Exemptions From Adequate Directions for Use

§ 801.109 Prescription devices.

A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from section 502(f)(1) of the act if all the following conditions are met:

(a) The device is:

(1)(i) In the possession of a person, or his agents or employees, regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device; or

(ii) In the possession of a practitioner, such as physicians, dentists, and veterinarians, licensed by law to use or order the use of such device; and

(2) Is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice.

(b) The label of the device, other than surgical instruments, bears:

(1) The statement "Caution: Federal law restricts this device to sale by or on the order of a ####", the blank to be filled with the word "physician", "dentist", "veterinarian", or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device; and

(2) The method of its application or use.

(c) Labeling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented: *Provided, however,* That such information may be omitted from the dispensing package if, but only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device. Upon written request, stating reasonable grounds therefor, the Commissioner will offer an opinion on a proposal to omit such information from the dispensing package under this proviso.

(d) Any labeling, as defined in section 201(m) of the act, whether or not it is on or within a package from which the device is to be dispensed, distributed by or on behalf of the manufacturer, packer, or distributor of the device, that furnishes or purports to furnish information for use of the device contains adequate information for such use, including indications, effects, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to employ the device can use the device safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented. This information will not be required on so-called reminder—piece labeling which calls attention to the name of the device but does not include indications or other use information.

(e) All labeling, except labels and cartons, bearing information for use of the device also bears the date of the issuance or the date of the latest revision of such labeling.

§ 801.110 Retail exemption for prescription devices.

A device subject to § 801.109 shall be exempt at the time of delivery to the ultimate purchaser or user from section 502(f)(1) of the act if it is delivered by a licensed practitioner in the course of his professional practice or upon a prescription or other order lawfully issued in the course of his professional practice, with labeling bearing the name and address of such licensed practitioner and the directions for use and cautionary statements, if any, contained in such order.

§ 895.22 Submission of data and information by the manufacturer, distributor, or importer.

(a) A manufacturer, distributor, or importer of a device may be required to submit to the Food and Drug Administration all relevant and available data and information to enable the Commissioner to determine whether the device presents substantial deception, unreasonable and substantial risk of illness or injury, or unreasonable, direct, and substantial danger to the health of individuals. The data and information required by the Commissioner may include scientific or test data, reports, records, or other information, including data and information on whether the device is safe and effective for its intended use or when used as directed, whether the device performs according to the claims made for the device, and information on adulteration or misbranding. Any relevant information that is voluntarily submitted will also be reviewed.

(b) A manufacturer, distributor, or importer of a device required to submit data and information as provided in paragraph (a) of this section will be notified in writing by the Food and Drug Administration that such data and information shall be submitted. The written notification will advise the manufacturer, distributor, or importer of the device that the purpose for the request is to enable the Commissioner to determine whether any of the conditions listed in paragraph (a) of this section or §895.30(a)(1) exists with respect to the device such that a proceeding should be initiated to make the device a banned device. When the required data and information can be identified by the Food and Drug Administration at the time of the notification, the agency will provide such identification to the manufacturer, distributor, or importer of the device.

(c) The required data and information shall be submitted to the Food and Drug Administration no more than 30 days after the date of receipt of the request, unless the Commissioner determines that the data and information shall be submitted by some other date and so informs the manufacturer, distributor, or importer, in which case the data and information shall be submitted on the date specified by the Commissioner.

(d) If the data or information submitted to the Food and Drug Administration is sufficient to persuade the Commissioner that the deception or risk of illness or injury or the danger to the health of individuals presented by a device could be corrected or eliminated by labeling or change in labeling, or change in advertising if the device is a restricted device, the Commissioner will proceed in accordance with §895.25.

(e) If the data or information submitted to the Food and Drug Administration is insufficient to show that the device does not present a substantial deception or an unreasonable and substantial risk of illness or injury, or an unreasonable, direct, and substantial danger to the health of individuals, or if the manufacturer, distributor, or importer fails to submit the required information, the Commissioner may rely upon this insufficiency or failure to submit the required information in considering whether to initiate a proceeding to make the device a banned device under §895.21(d) and, when appropriate, to establish a special effective date in accordance with §895.30. The Commissioner may also initiate other regulatory action as provided in the act or this chapter.

§ 895.25 Labeling.

(a) If the Commissioner determines that the substantial deception or unreasonable and substantial risk of illness or injury or the unreasonable, direct, and substantial danger to the health of individuals presented by a device can be corrected or eliminated by labeling or a change in labeling, or change in advertising if the device is a restricted device, the Commissioner will provide written notice to the manufacturer, distributor, importer, or any other person(s) responsible for the labeling or advertising of the device specifying:

(1) The deception or risk of illness or injury or the danger to the health of individuals,

(2) The labeling or change in labeling, or change in advertising if the device is a restricted device, necessary to correct the deception or eliminate or reduce such risk or danger, and

(3) The period of time within which the labeling, change in labeling, or change in advertising must be accomplished.

(b) In specifying the labeling or change in labeling or change in advertising to correct the deception or to eliminate or reduce the risk of illness or injury or the danger to the health of individuals, the Commissioner may require the manufacturer, distributor, importer, or any other person(s) responsible for the labeling or advertising of the device to include in labeling for the device, and in advertising if the device is a restricted device, a statement, notice, or warning. Such statement, notice, or warning shall be in the manner and form prescribed by the Commissioner and shall identify the deception or risk of illness or injury or the unreasonable, direct, and substantial danger to the health of individuals associated with the device as previously labeled. Such statement, notice, or warning shall be used in the labeling and advertising of the device for a time period specified by the Commissioner on the basis of the degree of deception, risk of illness or injury, or danger to health; the frequency of sale of the device; the length of time the device has been on the market; the intended uses of the device; the method of its use; and any other factors that the Commissioner considers pertinent.

(c) The Commissioner will allow a manufacturer, distributor, importer, or any other person(s) responsible for the labeling or advertising of the device a reasonable time, considering the deception or risk of illness or injury or the danger to the health of individuals presented by the device, within which to accomplish the required labeling, change in labeling, and, if the device is a restricted device, any change in advertising. The Commissioner may, however, request that no additional devices be introduced into commerce until the labeling or change in labeling, or change in advertising is accomplished by the manufacturer, distributor, importer, or other person(s) responsible for the labeling or advertising of the device.

(d) If such voluntary action is not taken, the Commissioner may take action under other sections of the act to prevent the introduction of the devices into commerce. The Commissioner may consider the failure of a manufacturer, distributor, importer, or any other person(s) responsible for the labeling or advertising of the device to accomplish the required labeling or change in labeling, or change in advertising in accordance with this section as a basis for initiating a proceeding to make a device a banned device in accordance with § 895.21(d) and when appropriate to establish a special effective date in accordance with § 895.30.

§ 895.30 Special effective date.

(a) The Commissioner may declare a proposed regulation under § 895.21(d) to be effective upon its publication in the FEDERAL REGISTER and until the effective date of any final action taken respecting the regulation if:

(1) The Commissioner determines, on the basis of all available data and information, that the deception or risk of illness or injury associated with use of the device that is subject to the regulation presents an unreasonable, direct, and substantial danger to the health of individuals, and

(2) Before the date of the publication of such regulation, the Commissioner notifies the domestic manufacturer and importer, if any, of the device that the regulation is to be made so effective. If necessary, the Commissioner may also notify the distributor or any other responsible person(s). In addition, the Commissioner will attempt to notify any foreign manufacturer when the name and address of the foreign manufacturer are readily available.

(b) This procedure may be used when the Commissioner determines that the potential or actual injury involved is a serious one that the Commissioner believes will endanger the health of individuals who have been, or will be, exposed to the device. In assessing the degree of danger, the Commissioner need not find that the danger is immediate, and it shall be sufficient for the Commissioner to determine that the danger may involve a serious long-term risk.

(c) If the Commissioner makes a proposed regulation effective in accordance with this section, the Commissioner will, as expeditiously as possible, give interested persons prompt

"(d) To shift the cost of hazardous waste cleanups more onto offenders and less onto law-abiding taxpayers.

"The people hereby enact the provisions of this initiative in furtherance of these rights."

Sections 6, 7 and 8 of Initiative Measure, Nov. 4, 1986, provide:

"Sec. 6. If any provision of this initiative or the application thereof is held invalid, that invalidity shall not affect other provisions or applications of the initiative which can be given effect without the invalid provision or application, and to this end the provisions of this initiative are severable.

"Sec. 7. To further its purposes this initiative may be amended by statute, passed in each house by a two-thirds vote.

"Sec. 8. This initiative shall take effect on January 1, 1987."

Amendment of this section by Stats.1990, c. 407 (Prop. 141) was rejected at the Nov. 6, 1990, general election.

Law Review Commentaries

California's toxics initiative: Making it work. Note, 39 Hast.L.J. 1195 (1988).

Problems with Prop. 65: Will California's toxics initiative hold water? James Dragna, 10 L.A.Law. 18 (April 1987).

§ 25249.6. Required warning before exposure to chemicals known to cause cancer or reproductive toxicity

No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual, except as provided in Section 25249.10.

(Added by Initiative Measure, Nov. 4, 1986, eff. Jan. 1, 1987.)

Historical and Statutory Notes

Purpose and effective date of Initiative Measure, Nov. 4, 1986, see Historical and Statutory Notes under § 25249.5.

Amendment of this section by Stats.1990, c. 407 (Prop. 141) was rejected at the Nov. 6, 1990, general election.

Law Review Commentaries

Problems with Prop. 65: Will California's toxics initiative hold water? James Dragna, 10 L.A.Law. 18 (April 1987).

Notes of Decisions

Occupational safety and health plan 2
Preemption 1

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1. Preemption

The Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C.A. § 136v] did not preempt this section to extent that it merely imposed restrictions on pesticide sale or use, without requiring additions to or deletions from pesticide package labels; many warning methods, including point-of-sale signs currently designated "safe harbor" under this section, could satisfy requirements of California without infringing on federal supremacy in area of pesticide labeling. D-Con Co., Inc. v. Allenby, N.D.Cal.1989, 728 F.Supp. 605.

Principles of comity would not counsel against Court of Appeal's exercising jurisdiction over petition for mandamus ordering state Occupational Safety and Health Standards Board to include in state plan warning and enforcement provisions of this chapter, although manufacturers' association had sought federal declaratory and injunctive relief that this chapter was preempted in the workplace by federal Occupational Safety and Health Act (OSHA) [29 U.S.C.A. § 651 et seq.] because federal hazard communication standard requires employers to warn employees of potential exposure to certain hazardous materials in workplace and state act related to same occupational safety and health issue. California Labor Federation, AFL-CIO v. California Occupational Safety and Health Standards Bd. (App. 1 Dist.1990) 271 Cal.Rptr. 310, 221 Cal.App.3d 1547, review denied.

2. Occupational safety and health plan

Court of Appeal had power to entertain mandamus petition by labor and environmental